



APR 29 2005

Dear Tribal Leader:

The purpose of this letter is to inform Tribes, Tribal organizations, and Urban Indian programs (T/Us) of activities essential to successful implementation of the Medicare Prescription Drug Benefit (Medicare Part D). This permanent drug benefit authorized in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, begins January 1, 2006, with the expiration of the Medicare Prescription Drug Discount Card and the Transitional Assistance program. This drug benefit will provide a new resource for Medicare beneficiaries who may not have had coverage to receive drugs through enrollment in a Medicare Prescription Drug Plan (PDP) or Medicare Advantage Plan (MA-PD), otherwise known as "Medicare Part D" plans. The IHS Medicare beneficiaries who receive drug coverage through Medicaid will be required to convert to the Medicare Prescription Drug Benefit. To receive reimbursement, the Indian Health Service (IHS), Tribes, Tribal organizations, and Urban Indian programs (I/T/Us) will be required to bill the various Medicare Part D plans that enroll our patients.

You will need to be aware of the following items as you start to prepare for the Medicare Prescription Drug Benefit:

1. **Billing** – To be able to bill for pharmaceuticals, sites will need a seven-digit National Council for Prescription Drug Programs (NCPDP) or an Alternate Site Enumeration Program (ASEP) number. The NCPDP number is a unique identifier for pharmacies to use when they bill third-party payers for pharmaceuticals. The ASEP number is an identifier for sites without a pharmacy where prescribers dispense medications. These sites are also known as dispensaries. Information about the NCPDP and ASEP programs is available at http://www.ncdp.org/main_frame.htm. Once at this Web site, click on "NCPDP Provider ID." While almost all T/U pharmacies have an NCPDP number, very few sites without pharmacies have an ASEP number. Either an NCPDP or an ASEP number will be needed when T/U sites sign contracts or billing agreements with Medicare Part D plans.

Medicare Part D plans do not have a listing of T/U dispensaries and will not send contracts or agreements to them unless the T/U dispensaries contact the individual plan directly or provide contact information to IHS Headquarters. The dispensaries can send their contact name, address, phone number, and e-mail address to CAPT Robert Pittman, IHS Principal Pharmacy Consultant, IHS Headquarters, to be added to the list of I/T/U pharmacies that will be made available to the Part D plans.

2. **Training** – The IHS and Centers for Medicare and Medicaid Services (CMS) are planning two training sessions per IHS Area on the Medicare Prescription Drug Benefit. The first training session for each Area is scheduled for May or June 2005 (see Attachment A –

Training Information). The T/Us will need to work with the Area Office point of contact to ensure that appropriate individuals (e.g., from patient registration, the billing office, and the pharmacy) at each site attend these training sessions. The second training for each Area is expected to take place in September 2005.

3. Contracting – Current Medicaid beneficiaries who are eligible for Medicare will have their prescription drug coverage changed from Medicaid to a Medicare PDP or an MA-PD starting on January 1, 2006. The I/T/Us will need to have contracts or agreements in place with Medicare Part D plans to be able to bill for medications dispensed to Medicare beneficiaries. The IHS, the CMS, Tribal Technical Advisory Group (TTAG), and Tribal consultants developed IHS-specific and T/U-program-specific addenda for Part D plans to use when developing contracts or agreements for I/T/U pharmacies and dispensaries (see Attachment B – Current Status of Part D Implementation and Attachment C - T/U program addendum).

The I/T/Us may receive up to 40 contracts or agreements from the Part D plans asking I/T/U pharmacies to participate in the plans' pharmacy network. The T/Us will need to review these contracts or agreements, negotiate any needed changes, and have contracts or agreements in place by early summer 2005 (most plans will ask for a 45-day turn around time). The T/Us will need to review the contracts to determine if the addendum issues are addressed, if the proposed reimbursement rate is acceptable, and if there are any T/U-specific issues they wish addressed.

The IHS direct care sites have been asked not to proceed with the contracting process but to report plan contact information to CAPT Pittman. A contract or agreement addendum specific to IHS direct care sites has been developed (go to <http://www.cms.hhs.gov/pdps/ihsaddendum021605.pdf>). The IHS Headquarters staff will review plan contracts or agreements for all IHS direct sites, negotiate changes as needed, and complete the contracting process.

4. Outreach and Education – The T/Us are encouraged to develop outreach and education plans, programs, and materials to inform staff and beneficiaries about the Medicare Prescription Drug Benefit and the process for completing the Low Income Subsidy (LIS) Application (to be mailed to beneficiaries by the Social Security Administration in May 2005). The LIS will assist individuals with premium payments, deductions, and cost share payments. Each IHS Area Office and CMS staff will be available to assist in this process.
5. The CMS Web site – The CMS Tribal Government Information Web site will provide periodic updates about the Medicare Prescription Drug Benefit for Tribal Leaders. Tribal Leaders and Urban Program Directors are encouraged to visit the CMS Web site frequently at <http://www.cms.hhs.gov/medicarereform/pdbma/tribal.asp>.

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Additional information and materials are enclosed providing basic information about the Medicare Prescription Drug Benefit (see Attachment D). If you have questions about this program, please contact your Area Office point of contact, or contact CAPT Pittman at (301) 443-1190 or Robert.pittman@ihs.gov.

Sincerely yours,

A handwritten signature in cursive script that reads "Charles W. Grim, DDS".

Charles W. Grim, D.D.S., M.H.S.A.
Assistant Surgeon General
Director

Enclosures

Attachment A- Medicare Part D Training Information
Attachment B- Current Status of Part D Implementation
Attachment C- T/U Program Addendum
Attachment D- Summary of Medicare Prescription Drug Benefit

ATTACHMENT A

(Training dates and agenda subject to change, please confirm with IHS Area Contact)

MEDICARE PRESCRIPTION DRUG BENEFIT (PART D) TRAINING

CMS REGION	IHS AREA	DATE	LOCATIONS
Denver and Kansas City	Aberdeen	June 2nd	Best Western Ramkota, Aberdeen, SD
Dallas	Albuquerque	May 17th	TBD
Seattle	Alaska	June 7th, 8th or 9th	TBD
Chicago	Bemidji	May 25th	Michigan
Denver	Billings	May 25th	Billings
Seattle	California	May 24th or 26th	TBD
Boston, New York & Atlanta	Nashville	May 9th or 12th	TBD
San Francisco and Dallas	Navajo	May 27th	TBD
Dallas & Kansas City	Oklahoma	May 24th	Reed Center, Midwest City, OK
San Francisco	Phoenix	TBD	TBD
Seattle	Portland	June 15th or 16th	TBD
San Francisco	Tucson	TBD	TBD

AGENDA - AWARENESS TRAINING ON MEDICARE PRESCRIPTION DRUG COVERAGE

8:30 - 8:45 - Introduction and Opening Prayer – Indian Health Service (IHS) staff

8:45 - 9:00 - Overview of Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG) TAG and TTAG Resources - TTAG member or representative

9:00 - 10:30 - Overview of Medicare Prescription Drug Coverage (key messages, eligibility and enrollment, limited income provisions, drug coverage, coordination with other coverage) and other Medicare Modernization Act (MMA) topics - CMS Staff

10:30 - 10:45 - Break

10:45 - 11:30 – Social Security Administration (SSA) role in MMA Implementation – Extra Help paying for prescription drugs (timeline for implementation and enrollee communication, application and approval process, SSA outreach activities, and coordination with Tribes) - SSA staff

11:30 - 12:00 - Questions and Answers - CMS, IHS and SSA staff

12:00 - 1:00 - Lunch

1:00 - 3:00 – Planning and Conducting Outreach & Education and specialty areas such as pharmacy contracts, further information on LIS outreach, coordination with State Medicaid Offices, other counseling and informational resources and additional topics as determined by

Area Offices- IHS staff, CMS Staff, SSA staff, State Medicaid staff, and State Health Insurance Counseling Program staff

3:00 - 3:15 - Break

3:15 - 4:30 - Recap Summary, Final Questions and process to get back with answers, Resources for ongoing information, Next steps, Evaluation - IHS and CMS staff

***INDIAN HEALTH SERVICE AREA OFFICE POINT OF CONTACTS
MEDICARE PART D AND LOW INCOME SUBSIDY***

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KEY MEDICARE DATES**January 2005**

January 1, beneficiaries can take advantage of preventative screening services:

“Welcome to Medicare” Physical Exam
 Cholesterol and other Cardiovascular Screening
 Diabetes Screening

February 2005

February 18, Prescription Drug Plans (PDPs) and Medicare Advantage plans (MA-PD) are required to submit “Notice of Intent” to CMS to participate in Medicare Part D

March 2005

March 23, deadline for receipt of applications by CMS from PDPs and MA-PDs

March 31, last day for low-income beneficiaries to apply and receive the full \$600 credit from the Medicare Prescription Drug Discount Card

April 2005

April 18, deadline for PDP and MD-PD plan formularies to be submitted to CMS

Beneficiaries should visit www.medicare.gov to see if they are eligible for extra help paying for prescription drugs

PDPs and MA-PDs will start mailing Pharmacy Network Agreements to Tribal and Urban Program pharmacies with most asking for a 90 day turn around time (agreements will be mailed to Chief Pharmacists who will need to get the agreements to the appropriate Tribal or Urban Program contracting official)

CMS to send instructions to States on how to process dual eligible beneficiaries.

SSA starts outreach and education campaign and training of third parties about Low Income Subsidy (LIS)

May 2005

May 27, information will be mailed to Medicare beneficiaries by Social Security about applying for extra help with drug plan costs

The IHS Area Offices and CMS Regional Offices will start training I/T/U sites about the Medicare Prescription Drug Benefit

June 2005

June 6, PDP and MA-PD bids are due to CMS (premium costs)

June 7, PDPs and MA-PDs may submit marketing materials to CMS for review.

June 30, last day for low-income beneficiaries to apply for and receive the \$450 Credit from the Medicare Prescription Drug Discount Card

July 2005

July 1, low income beneficiaries can apply for extra help with drug plan costs through the Social Security Administration web site at www.socialsecurity.gov

July 15, PDPs and MA-PDs must meet beneficiary pharmacy access standards (therefore plans will want to have all pharmacy agreements finalized by this date)

August 2005

August 1, PDP and MA-PD access standards must submitted to CMS (this includes a list showing the current status of agreements with all I/T/U pharmacies and dispensaries - an agreement in place, negotiating a contract or the I/T/U declined to contract with the plan)

August 4, CMS to announce national average monthly bid amount and call for reallocations.

September 2005

Early September, CMS contracting with PDPs and MA-PDs should be complete

The IHS Area Offices and CMS Regional Offices will hold Area level training for I/T/U sites related to outreach, education and implementation for the Medicare Prescription Drug Benefit

September 30, last day for low-income beneficiaries to apply for and receive the \$300 credit from the Medicare Prescription Drug Discount Card

October 2005

October 1, PDPs and MA-PDs can begin marketing to beneficiaries

October 13, beneficiaries can compare the benefits from Medicare Prescription Drug Plans at www.medicare.gov or by calling 1-800-MEDICARE

Late October, beneficiaries will receive the “Medicare & You” handbook via mail

Medicare will send letters to beneficiaries who will be automatically enrolled in the Medicare Drug Benefit Program

Retirees who have health benefits will begin to receive information from their former employer or union

November 2005

November 15, beneficiaries can enroll in the PDP or MA-PD of their choice (open enrollment through May 31, 2006)

November 30, last day for low-income beneficiaries to apply for and receive the \$150 credit from the Medicare Prescription Drug Discount Card

January 2006

Start of the Medicare Prescription Drug Benefit - patients who are eligible for both Medicare and Medicaid (dual eligible) will no longer receive a prescription drug benefit through Medicaid

ATTACHMENT B

CURRENT STATUS OF PART D IMPLEMENTATION

In January 2006, 41 million people with Medicare, including an estimated 60,000 to 70,000 American Indian and Alaska Natives, will have the option of enrolling in a plan that covers prescription medications. These plans will be offering prescription drug coverage, which is different from discounts that were offered by the Medicare-approved drug discount cards. CMS contracts with private drug plans (PDPs) or Medicare Advantage plans (MA-PD) to negotiate discounted prices on behalf of their enrollees. Insurance companies and other appropriate organizations bid to serve as prescription drug plans. The IHS, the CMS Tribal Technical Advisory Group (TTAG) and CMS staff worked to make sure the final regulations for Medicare Part D took into account health care services in Indian country. The final regulations for Medicare Part D were published by CMS on January 28, 2005 (available at <http://www.cms.hhs.gov/medicarereform/>).

As part of the preparation process, IHS, TTAG and CMS staff felt there was a need to provide guidance to prospective plans about applicable laws, and regulations that would potentially impact the contracting process with Tribes and Urban programs. To that end, the IHS, TTAG and CMS staff developed a Tribal/Urban program addendum for Part D plans to use when creating their contracts or agreements for T/U pharmacies and dispensaries (see Attachment C). Plans have reviewed this document, developed their pharmacy contracts or agreements and have submitted their proposed contracts to CMS for review and approval. Plans are expected to submit contracts or agreement to T/U pharmacies throughout April and May 2005. Some Tribal sites have already reported receiving Part D plan contracts or agreements. Pharmacists working at Tribal or Urban programs, have been asked to contact the Tribe or hospital or clinic Chief Executive Officer to determine who is the appropriate individual to review and negotiate contracts or agreements for the Tribe or Urban program. Some sites may receive 20 or more contracts or agreements with short turn around times.

Pharmacists at IHS direct care sites have been asked not to proceed with the contracting process but to report plan contact information to CAPT Robert Pittman, Principal Pharmacy Consultant. A contract or agreement addendum specific to IHS direct care sites has been developed (go to <http://www.cms.hhs.gov/pdps/ihsaddendum021605.pdf>) The IHS Headquarters staff will review plan contracts or agreements for all IHS direct sites, negotiate changes as needed and complete the contracting process.

The IHS, TTAG and CMS staffs have been developing Outreach and Education training programs to train I/T/U sites about the Medicare Part D Prescription Drug Benefit. Two in person trainings will take place in each IHS Area in 2005. The first trainings will take place in May 2005 and will educate staff about the benefit, the contracting process, how to assist beneficiaries in completing the Social Security Low Income Subsidy paperwork and how sites can prepare for outreach and education efforts for their local beneficiaries. A second training will take place in each IHS area in September 2005. This training will provide a final update on approved plans, give additional information about auto enrollment of dual eligible beneficiaries and provide an update on claims processing using the IHS Point of Sale billing package. In addition to the formal training sessions, IHS and CMS plan 3 or 4 nationwide conference calls to provide updates and allow Service Unit staff the opportunity to ask questions and bring up issues. A question and answer sections will be added to both the IHS and CMS Medicare websites where Tribes and staff can go to see questions and answers from the conference calls and from staff who have contacted IHS headquarters or CMS.

ATTACHMENT C

TRIBE AND URBAN PROGRAM CONTRACT ADDENDUM FOR MEDICARE PART D PLAN AGREEMENTS

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____ (herein "Part D Plan Sponsor") and _____ (herein "Provider") for administration of Medicare Prescription Drug Benefit program at pharmacies and dispensaries of Provider authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422 and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Part D Plan Sponsor's agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Part D Plan Sponsor's agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR Part 423 or 42 CFR Part 422 as meeting the requirements and standards that apply to entities that offer Medicare prescription drug plans.

(b) The terms "Part D Plan" means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272, 42 CFR 422.502 or 42 CFR 417.472 and that is offered by a PDP sponsor that has a contract with the Centers for Medicare and Medicaid Services that meets the contract requirements under subpart K of 42 CFR Part 423 or subpart K of 42 CFR Part 422.

(c) The term "Provider" means an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(k) The term "dispensary" means a clinic where medicine is dispensed by a prescribing provider.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

☐ ☐ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*

☐ ☐ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*

☐ ☐ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Deductibles.

The cost of pharmaceuticals provided at a pharmacy or dispensary of Provider or paid for by the Provider through a referral to a retail pharmacy shall count toward the deductible applicable to an IHS beneficiary enrolled in a Part D Plan.

5. Persons eligible for services of Provider.

(a) The parties agree that the persons eligible for services of the Provider shall be governed by the following authorities:

- (1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Part 403 of Title 42, Code of Federal Regulations;
- (2) Sec. 813(a) and Sec. 813(c) of the Indian Health Care Improvement Act, 25 USC §1680c (a) and (c);
- (3) Part 136 of Title 42, Code of Federal Regulations; and
- (4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program, including one or more pharmacies or dispensaries.

(b) No clause, term or condition of the Part D Plan Sponsor's agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Part D Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to Provider as noted:

(a) A Provider who is an Indian tribe or a tribal organization:

- (1) The Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*;
- (2) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.*;
- (3) The Federal Tort Claims Act, 28 USC §2671-2680;
- (4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
- (5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(b) A Provider who is an urban Indian organization:

- (1) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.*;
- (2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
- (3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian

- organization is a Federally Qualified Health Center;
- (4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

To the extent the Provider is a non-taxable entity, the Provider shall not be required by a Part D Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain general liability, professional liability or other insurance, as such Provider is covered by the Federal Tort Claims Act pursuant to Federal law (Pub.L. 101-512, Title III, §314, Nov. 5, 1990, 104 Stat. 1959, as amended by Pub. L. 103-138, Title III, §308, Nov. 11, 1993, 107 Stat. 1416 (codified at 25 USC §450f note); and regulations at 25 CFR Part 900, Subpt. M. To the extent a Provider that is an urban Indian organization is covered by the FTCA pursuant to section 224 of the Public Health Service Act (codified as 42 U.S.C. §233), and regulations at 42 C.F.R. Part 6, such Provider shall not be required to obtain or maintain general liability, professional liability or other insurance as such Provider is covered by the Federal Tort Claims Act pursuant to such designation. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify the Part D Plan Sponsor.

9. Employee license.

Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of Provider, such employee is not subject to regulation of qualifications by the State in which Provider is located. The parties agree that during the term of the Pharmacy Agreement, such Federal employees will be licensed in accordance with applicable Federal statutes and regulations. To the extent that any direct employee of Provider is exempt from State regulation, such employee shall be deemed qualified to perform services under the Part D Plan Sponsor's agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements, the Provider shall not be required to hold a State license to receive any payments under the Part D Plan agreement and any addendum thereto.

11. Dispute Resolution.

In the event of any dispute arising under the Participating Pharmacy Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Pharmacy Agreement.

12. Governing Law.

The Part D Plan Sponsor's agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between such agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall subject Provider to State law to any greater extent than State law is already applicable.

13. Pharmacy/Dispensary Participation.

The Part D Plan Sponsor's agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the Schedule B to this Indian Health Addendum. A pharmacy is required to use a National Council for Prescription Drug Programs (NCPDP) provider number for reimbursement. To the extent a dispensary does not have a NCPDP provider number, it is required to use an NCPDP Alternate Site Enumeration Program (ASEP) number for reimbursement.

14. Acquisition of Pharmaceuticals.

Nothing in the Part D Plan Sponsor's agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in such agreement and all addenda thereto require the Provider to acquire drugs from the Part D Plan Sponsor or from any other source.

15. Point of Sale Processing.

Where the Part D Plan Sponsor's standard pharmacy agreement contains provisions related to drug utilization review and/or generic equivalent substitution and the Provider does not have the reasonable information technology capacity to comply with such, then the provisions shall not apply to the Provider. As specified in §423.132(c)(3) of the final rule, the notification of price differentials is waived for the Provider.

16. Claims.

The Provider may submit claims to the Part D Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim.

17. Payment Rate.

Claims from the provider shall be paid at rates that are reasonable and appropriate.

18. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan Sponsor to Provider in paper and electronic format at no cost to the Provider.

19. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Part D Plan Sponsor, Provider shall provide written notification of its hours of service.

ATTACHMENT D

MEDICARE PRESCRIPTION DRUG BENEFIT

The Medicare Prescription Drug, Improvement and Modernization Act (MMA) has several provisions that affect Indian country. This particular document will discuss the Medicare Prescription Drug Benefit (Part D). Beginning January 1, 2006, people with Medicare have the option to enroll in a plan that covers prescription drugs. These plans offer prescription drug coverage, which is different from discounts that were offered by the Medicare-approved drug discount cards. CMS contracts with private companies offering prescription drug plans (PDPs) to negotiate discounted prices on behalf of their enrollees. Insurance companies and other appropriate organizations bid to serve as prescription drug plans. People with Medicare can also receive drug benefits through their Medicare Advantage plan (MA-PD) if they are enrolled in one. Some employers and unions may also provide coverage to people with Medicare.

A person with Medicare who is eligible for Medicare prescription drug coverage can enroll in a PDP or MA-PD to receive medication coverage. There are 34 regions for the PDPs. The smallest service area is a state and the largest is comprised of seven states. Plans have to offer identical benefits at identical premiums to every Medicare beneficiary in a region. However, the premium amount can vary among regions. The MA-PD plans, including the new Preferred Provider Organizations (PPO), operate in 26 regions.

Medicare PDPs, must offer a basic drug coverage (standard benefit). They may choose to offer supplemental benefits through enhanced alternative coverage for an additional premium. The PDPs have flexibility in how they design their prescription drug coverage. For example, they can establish a formulary to designate specific drugs that will be available within each class of therapeutic medications, or they can have cost-sharing structures other than the standard benefit structure. A formulary is the entire list of drugs covered by a PDP or MA-PD.

Eligibility

Anyone who has Medicare Part A and/or Part B is eligible to join a Medicare prescription drug plan. A person must live in the service area of a prescription drug plan to enroll. Individuals who reside outside of the U.S. or who are incarcerated are ineligible to enroll in a PDP or MA-PD plan and therefore are not eligible for this coverage. A person must enroll in a plan (PDP or MA-PD) to get Medicare prescription drug coverage.

Enrolling

Eligible people with Medicare will **enroll directly with the PDP or MA-PD**. These individuals can elect to select their own plan rather than the one assigned by Medicare. People with Medicare can enroll themselves directly in a plan, they can use a personal representative who has the legal authority to enroll them, or they can enlist the assistance of others to help them enroll. Plans are required to process applications in a timely manner, and the plan must notify the applicant of acceptance or denial of the enrollment request.

Enrollment Options

People who are in the Original Medicare Plan will receive their Medicare prescription drug coverage through a PDP. People enrolled in a Medicare Advantage plan will receive their coverage through that plan. There are exceptions to this rule:

- If a person with Medicare is in a Private Fee-for-Service (PFFS) Plan with no qualified prescription drug coverage or has a Medical Savings Account (MSA), he or she can enroll in a PDP.
- People with Medicare enrolled in a Program of All-inclusive Care for the Elderly (PACE) plan that offers qualified prescription drug coverage must obtain the drug plan benefit through that PACE plan. PACE combines medical, social, and long-term care services for frail people.
- People enrolled in a cost-based Health Maintenance Organization (HMO) have the option either to get Medicare prescription drug coverage from the plan, if it is offered, or to enroll in a PDP.
- If the person with Medicare is in an MA plan with prescription drug coverage on December 31, 2005, or the MA plan will offer Medicare prescription drug coverage in 2006, they will be enrolled in the MA-PD plan starting on January 1, 2006.

Enrollment Periods

There are three enrollment periods.

- The Initial Enrollment Period (IEP) allows people to enroll in a Medicare prescription drug plan when they are first eligible for Medicare prescription drug coverage.
- The Annual Coordinated Election Period (AEP) allows people to change their Medicare prescription drug plan, enroll in a prescription drug plan, or disenroll from a Medicare prescription drug plan.
- And last is the Special Enrollment Periods (SEP).

For the start of the drug coverage, the IEP is from November 15, 2005, to May 15, 2006, for individuals who

- Are currently eligible, or
- Become eligible in November and December 2005, and January 2006

For people who become eligible for Medicare after January 2006, the initial enrollment period is similar to the initial enrollment period for Part B. This is a 7-month enrollment period, including

- 3 months before eligibility for Medicare prescription drug coverage
- the month of eligibility
- 3 months after eligibility for Medicare prescription drug coverage

For the first year, the AEP is the same as the Initial Enrollment Period: from Nov 15, 2005, to May 15, 2006. In 2006 and after, the AEP is from November 15 to December 31 of each year.

There are circumstances in which people with Medicare are given a SEP. These include:

- When an individual permanently moves out of the plan service area
- Involuntary loss, reduction, or non-notification of creditable coverage. This does not apply when creditable coverage is lost due to non-payment of premiums. If people with Medicare were not adequately informed that their coverage was not creditable or that

their current coverage was reduced so that it is no longer creditable, then they qualify for a SEP.

- When an individual is entering, residing in, or leaving a long-term care facility, or
- Exceptional circumstances such as when a PDP terminates its contract or a PDP violates its contract.

Full-benefit dual eligible beneficiaries (those that have both Medicare and Medicaid) have a continuous Special Enrollment Period. They can change their Medicare prescription drug plan at any time.

Generally, a person remains enrolled in a Medicare prescription drug plan for a year. If the person doesn't choose a plan during the Annual Coordinated Election Period, he or she may not enroll in a plan until the next Annual Coordinated Election Period or a Special Enrollment Period, if the person has one.

Disenrollment

People **must** be disenrolled from a Medicare prescription drug plan if:

- They move out of the service area
- They lose entitlement to Part A benefits and are no longer enrolled in Part B
- They pass away
- Their PDP's or MA-PD's contract is terminating
- They misrepresent information to the PDP sponsor that they have or expect to receive reimbursement for third party coverage.

People **may** be disenrolled (at the plan's option) if they:

- Do not pay their plan premiums on a timely basis
- Exhibit disruptive behavior.

Postponing Enrollment

If a person with Medicare chooses not to join a Medicare prescription drug plan at the first opportunity, he or she may have to pay a higher premium if he or she decides to enroll later. Exceptions: If someone has prescription drug coverage that covers at least as much as a Medicare prescription drug plan, then he or she may keep the current coverage. He or she will not have to pay a higher premium to enroll in a Medicare prescription drug plan at a later date. **IHS is considered creditable coverage for Medicare Part D.**

If someone has prescription drug coverage that covers less than a Medicare prescription drug plan, he or she can:

- (1) keep the current drug plan and join a Medicare prescription drug plan to provide more complete coverage, or
- (2) just keep the current drug plan. But if he or she joins a Medicare prescription drug plan later, then he or she will have to pay a higher premium; or
- (3) drop the current plan and join a Medicare prescription drug plan. But he or she may not be able to get the other coverage back.

The higher premium is 1% of the base premium for each month the person did not have creditable coverage. Creditable coverage is coverage that is as good as Medicare prescription drug coverage. People will pay the higher premium for as long as they are enrolled in a

Medicare prescription drug plan. People who qualify for the extra help and are subject to the higher premium due to late enrollment will receive additional assistance to help pay for the higher premium. The additional premium subsidy is equal to 80% of the late enrollment higher premium for the first 60 months during which the higher premium is imposed and 100% of their late enrollment premium thereafter.

Some examples of coverage that is at least as good as Medicare prescription drug plan coverage may include:

- Coverage under a Medicare prescription drug plan or Medicare Advantage prescription drug coverage
- Group Health Plans (GHP)
- State Pharmaceutical Assistance Program (SPAP)
- VA coverage
- Indian Health Service
- Military coverage including TRICARE

Medigap may or may not be creditable coverage. (e.g., plans in the waiver states – Minnesota, Massachusetts, and Wisconsin as well as some of the “rich” plans sold prior to the standardization may be creditable.)

People who have other prescription drug coverage will get a notice from their plan that tells them if the plan covers at least as much as a Medicare prescription drug plan. The plan will also notify them if the coverage changes so that it is no longer as good as Medicare prescription drug coverage.

Medicare Advantage Election Periods

Medicare Advantage election periods are similar to PDP enrollment periods with the addition of the Open Enrollment Period. There are four MA election periods.

- The Initial Coverage Election Period (ICEP)
 - 7-month period surrounding Medicare entitlement (Part B Initial Enrollment Period)
 - 3 months prior to entitlement to Part A and Part B
- The Open Enrollment Period (OEP)
 - In 2006: Nov. 15, 2005, through May 15, 2006
 - In 2007 and beyond: Nov. 15 through Dec. 31

Someone cannot use the OEP to change whether or not he or she is enrolled in Medicare prescription drug coverage but he could elect Original Medicare and a PDP, but he could not drop Medicare prescription drug coverage by electing an MA only (i.e., not an MA-PD) plan.

- The Annual Coordinated Election Period (AEP) and
- Special Election Periods (SEPs).

Enrolling in a Plan

Eligible people with Medicare enroll directly with the PDP or MA-PD. In the fall of 2005, people with Medicare will receive the *Medicare & You 2006* handbook in the mail, which will include information about Medicare prescription drug plans available in their area. There are other information sources to help people with Medicare choose a plan. In the fall of 2005, prescription drug plan information will be available and posted on the www.medicare.gov website. The MA-PD plan information will replace the Medicare

Personal Plan Finder (MPPF) and the PDP information will replace PDAP (Prescription Drug and Other Assistance Program database). There will be one portal of entry using a series of questions to get to the information you need. It will be simple and easy to use.

People can also call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048, and State Health Insurance Assistance Programs (SHIP). The *Medicare & You* handbook contains the local telephone number.

Auto-enrollment of Dual Eligible Beneficiaries

Dual eligibles (people with Medicare and full Medicaid benefits) will no longer receive their drug coverage through Medicaid, but rather from Medicare through a PDP or MA-PD. They will be automatically enrolled by CMS in a PDP or MA-PD if they do not select one on their own by December 31, 2005. However, they will have a special enrollment period if they decide to change plans at a later date. CMS will mail a notice to full-benefit dual eligibles in October 2005 that will encourage them to choose a plan and let them know that if they don't enroll in a plan, Medicare will enroll them in a plan.

Facilitated Enrollment

CMS is also enrolling additional people with Medicare who qualify for extra help if they do not choose a plan on their own by May 15, 2006. These include people with Medicare receiving Supplemental Security Income (SSI), people with Medicare who are in a Medicare Savings Program such as Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or Qualifying Individual (QI), and people who apply and are determined eligible for the extra- help. Their coverage is effective June 1, 2006. These people receive state help paying for their Medicare deductibles, premiums, and copayments. When CMS facilitates enrollment, the agency will follow the same rules as those used for auto-enrollment.

Long Term Care Facilities

Generally, long-term care facilities (i.e., nursing homes and skilled nursing facilities) contract with one long-term care pharmacy to supply the prescription drugs needed by the residents. With the implementation of Medicare prescription drug plans, these long-term care pharmacies will have to contract with both the facility and the Medicare prescription drug plans serving the region.

Web Self-Service Application

In April 2005 a tool is available to give people with Medicare information on Medicare prescription drug coverage and on the extra help with drug plan costs. A Web-based calculator helps people determine if they are eligible for the extra help and tells them what to expect and what they need to do, if anything. This information will be closely matched to the information being mailed.

In October 2005, the Medicare Prescription Drug Plan Finder Tool is available. This tool contains plan information on each plan.

Extra Help with Premiums

The Extra Help (Low Income Subsidy) is designed to provide people with limited income and resources extra assistance with premium and cost sharing under the Medicare prescription drug coverage. A person must enroll in a Medicare prescription drug plan to receive Extra Help. An application for the Extra Help may be filed with either the Social Security Administration (SSA) or the state's Medicaid program office. CMS is strongly encouraging states to consider using the SSA application and to assist people in filing their applications with SSA. States may assist individuals who present themselves at state offices in completing the SSA application, with the state sending the completed applications to SSA for processing. The SSA application relies on self-attestation—a certification by an individual that the information is correct. There is a verification process that relies primarily on automated data matches with sources such as the IRS. The verification process may also involve some follow-up with the individual on an exception basis when additional information is needed. The office that processes the application, either SSA or the state Medicaid agency, will decide when and how often someone must reapply and how they can appeal a determination.

Certain groups of people with Medicare are “deemed” eligible, meaning that they do not have to apply for the assistance; they automatically qualify. People with Medicare can apply for the Extra Help by:

- Completing the SSA form that is sent to potential eligibles
- Applying on the SSA website
- Going to an SSA field office
- Going to a state Medicaid Office
- Working with community-based organizations

These are certain groups of people who are automatically considered eligible for the Extra Help. These include:

- Full-benefit dual eligibles (people with Medicare who also get full Medicaid benefits)
- People with Medicare who get Supplemental Security Income (SSI) but no Medicaid benefits.
- People with Medicare who qualify for a Medicare Savings Program (MSP) such as QMB (Qualified Medicare Beneficiary), SLMB (Specified Low-Income Medicare Beneficiary), or QI (Qualifying Individual).

All other people with Medicare must file an application.

CMS is mailing a notice to these groups in **May 2005** letting them know they automatically qualify for the Extra Help and do not need to apply. Starting in May through August of 2005, SSA is mailing an application to people who may qualify for the Extra Help (but will not be deemed eligible) and will begin processing applications on July 1, 2005. SSA will send the applicant a determination once the application is processed.

People with Medicare can apply on their own behalf for the Extra Help to pay for their prescription drug coverage. They may also enlist the help of a personal representative who has the authority to act on their behalf, such as Power of Attorney. They may also enlist the help of others such, as a spouse, family member, caregiver, or advocate.

Income

Income is counted using the rules of the Supplemental Security Income (SSI) program, including the treatment of Indian trust income and resources. Since the SSI rules are clear on what is income is counted, CMS goes by SSI rules. In terms of whose income to count, CMS looks at the income of the applicant and the spouse residing with the applicant, regardless of whether or not the spouse is applying for the Extra Help. The issues of what income to count and whose income to count are only half the equation. The other half is the standard against which to determine eligibility. The standard is the Federal poverty level standard appropriate to the size of the applicant's family. Basically, the size of the family takes into consideration whether the applicant or his or her spouse have dependent relatives who reside with them and who rely on them for at least half of their support. Thus, a grandparent raising grandchildren may qualify as a result of using a greater family size, but the same person might not have qualified as an individual. Extra Help is available to people with incomes below 150% of the Federal poverty level. Contact SSA for additional information on income requirements.

Resources

Resources are counted for an applicant and a spouse residing with the applicant and compared against a resource standard. Because this section does not actually define resources, and because the law envisioned a simplified application in which applicants attest to their level of resources and submit only minimal documentation, CMS was able to propose a streamlined definition of resources compared to what is normally used under the SSI. In order to keep the process simple and minimize administrative cost, only two resources are considered available to the applicant to pay for the Medicare prescription drug coverage premiums, deductibles, and co-payments:

- Liquid resources (e.g., savings accounts, stocks, bonds and other assets that could be converted to cash within 20 days) and
- Real estate does not include the applicant's primary residence or land on which the primary resident is located

Items such as wedding rings and family heirlooms are not considered resources for the purposes of the Extra Help.

Three groups have been identified for the extra help:

- Group 1 are full-benefit dual eligibles with incomes at or below 100% of the Federal poverty level (FPL).
- Group 2 are full-benefit dual eligibles above 100% of FPL; QMB, SLMB, QI, SSI-only, or non-dual eligible beneficiaries with incomes below 135% of the FPL, with resource limits of \$6,000 per individual and \$9,000 for a married couple.
- Group 3 are Medicare beneficiaries with incomes below 150% of the FPL, with resource limits of \$10,000 for an individual and \$20,000 for a married couple.

Cost sharing and premiums for **full-benefit dual eligible** beneficiaries on Medicaid who are institutionalized is \$0. In other words, they have no cost sharing, no premiums, no deductible.

People who are in **Group 1, full-benefit dual eligibles with incomes at or below 100% of FPL**, are not responsible for the monthly premium or the annual deductible. They are only responsible for small co-payments, \$1 for generics and \$3 for brand-name drugs. If the extra

help combined with these small co-payments reach \$3,600, the person would not be responsible for any other co-payments for the rest of the year.

People in **Group 2, full-benefit dual eligibles above 100% of FPL; QMB, SLMB, QI, SSI-only or non-dual eligible beneficiaries with incomes below 135% FPL and limited resources (\$6K/individual and \$9K/married couple)**, are not responsible for the monthly premium or the deductible. They have a \$2 co-payment for generic drugs and a \$5 co-payment for brand-name drugs. Here again, if the extra help and co-payments total \$3,600, the person would not have any other co-payments for the rest of the year.

For people in **Group 3, those with incomes below 150% FPL and limited resources (\$10K/individual and \$20K/married couple)**, the premium is based on a sliding scale depending upon the person's income. They are responsible for a reduced deductible of \$50 per year, and they will be responsible for 15% of the cost of their prescriptions up to the \$3,600 out-of-pocket maximum. Once they have reached that maximum, they will have a \$2 co-payment for generic drugs and a \$5 co-payment for brand-name drugs for the rest of the year.

Institutionalized full-benefit dual eligibles will not be responsible for any out-of-pocket costs.

NOTE: The premium for Groups 1 and 2 will only be \$0 if the person enrolls in a plan with a premium at or below the low-income subsidy amount. If someone chooses a plan with a premium that is greater than the amount of premium assistance available, then he or she is liable for the difference.

How Extra Help Works

CMS notifies the Medicare prescription drug plan of the plan member's eligibility for the Extra Help and the amount of the assistance. The PDP or MA-PD must reduce the enrollee's premium and cost sharing as applicable and provide CMS with the amounts of those reductions. The PDP or MA-PD must track the Extra Help amounts applied to the out-of-pocket threshold. The PDP or MA-PD must reimburse the person with Medicare, and/or organizations paying cost sharing on his or her behalf, for any excess premiums and cost sharing paid after the effective date of the extra help.

Out-Of-Pocket Threshold

What is the out-of-pocket threshold? This is the amount of money a person with Medicare must spend on PDP or MA-PD covered drugs **in a calendar year** to reach the catastrophic cap. In the standard benefit, the out-of-pocket threshold consists of the three amounts that a person with Medicare is responsible for paying:

- Deductible (\$250)
- 25% coinsurance in the initial coverage stage (\$500)
- 100% between \$2,250 - \$5,100 (\$2,850)

For 2006, the total out-of-pocket threshold amount is \$3,600. **The PDP or MA-PD premium is not part of the out-of-pocket threshold.**

Sources of payments for Medicare prescription drugs that **are counted** toward the out-of-pocket threshold include:

- The person with Medicare, as long as he or she is not reimbursed by an insurer

- Other individuals such as family members or friends, as long as they are not reimbursed by third party coverage
- Medicare's cost-sharing assistance for people with low incomes such as QMB, SLMB, or QI
- A qualified State Pharmacy Assistance Program (SPAP)
- A bona fide charity

A qualified SPAP allows the person with Medicare to enroll in any Medicare prescription drug plan available to him or her and does not steer the person into one plan or another to meet the eligibility requirements or receive higher assistance amounts. If it is a qualified SPAP, then payment counts toward the out-of-pocket threshold.

An unqualified SPAP steers the person with Medicare into one plan or another in order to become eligible for the program or to receive a certain level of assistance. Payments made by unqualified SPAPs do not count toward the out-of-pocket threshold.

The plan (PDP or MA-PD) will calculate the out-of-pocket threshold for beneficiaries.

The deductible does not have to be satisfied by out-of-pocket payments. It can be paid by insurance or another payer.

Here are some examples of sources of payments that **would not count** toward the out-of-pocket threshold:

- GHP (such as retiree coverage provided by a former employer or union)
- Governmental programs such as TRICARE, Black Lung, VA **and** IHS
- Worker's Compensation
- Automobile, no-fault, or liability insurance
- Supplemental benefit portions of PDP or MA-PD

Other payments that don't count toward the out-of-pocket threshold include:

- Payment made by any other third party payment arrangement
- Drugs purchased outside the U.S.
- Over-the-counter drugs
- Drugs not on the plan's formulary (sometimes drugs not on a plan's formulary may be approved for use through an appeals or grievance process and are then treated as being included in the formulary)

In general, Flexible Spending Accounts (FSA), Health Savings Accounts (HSA), Medical Savings Accounts (MSA), and Health Reimbursement Accounts (HRA) are not counted toward the out-of-pocket threshold. However, certain, HRAs may be counted, depending on the specific design. Also, payments for drugs considered not covered by law are not applied to the out-of-pocket threshold.

The plan (PDP or MA-PD) is required to calculate the out-of-pocket threshold. They will ask what other insurance coverage the person with Medicare has so that they can accurately calculate the out-of-pocket threshold. The plan will send the person a statement at least on a monthly basis showing how much has been spent for the year and where the person is in terms of reaching the out-of-pocket threshold for catastrophic coverage. If a person with

Medicare materially misrepresents the supplemental coverage, this constitutes grounds for termination of coverage from any Medicare prescription drug plan.

Once the \$3,600 in out-of-pocket costs threshold is met, the catastrophic coverage begins. When this occurs, Medicare will pay 80%, the Medicare prescription drug plan will pay 15%, and the person with Medicare will pay 5% of drug costs in that year. Wrap-around coverage, drug coverage that does not count toward the out-of-pocket threshold, is still beneficial because it provides coverage where the PDPs or MA-PDs do not, and essentially delays the start of the catastrophic coverage. Catastrophic coverage is not effective until the \$3,600 out-of-pocket threshold is met.

Medicare Prescription Drug Coverage

A Medicare-covered prescription drug must be available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication. A covered drug would include prescription drugs, biological products, and insulin. Medical supplies associated with the injection of insulin, such as syringes, needles, alcohol swabs, and gauze, are covered. (Used needle containers are not covered insulin supplies.)

Not all “covered drugs” will be covered by the PDP or MA-PD plan. Each plan may develop a formulary. A formulary is a list of preferred medications covered by the PDP or MA-PD. Each plan is required to meet certain standards for its formulary. For example, the plan formularies must be developed by a Pharmacy and Therapeutics Committee. The majority of the committee’s members must be physicians and practicing pharmacists. In addition, the formulary must include drugs in each therapeutic category and class of covered drugs.

The drugs excluded from Medicare prescription drug coverage are the same drugs that were excluded under the Medicare-approved drug discount card. These drugs are excluded by statute.

- Drugs for
 - Anorexia, weight loss, or weight gain
 - Fertility
 - Cosmetic purposes or hair growth
 - Symptomatic relief of cough and colds
- Prescription vitamins and mineral products
 - Except prenatal vitamins and fluoride preparations
- Non-prescription drugs
- Barbiturates
- Benzodiazepines

In addition, drugs covered under Medicare Part A or Part B are not covered under this part of Medicare (even though a deductible may apply).

Formulary

CMS relies on industry-recognized best practices for existing drug benefits to ensure non-discriminating, appropriate access for Medicare beneficiaries. CMS looks at drug classes and categories, specific drugs, utilization management tools, and appeals processes of plans to assure that people with Medicare are able to receive access to products in a non-

discriminatory and timely manner. Plans are given the flexibility in the benefit design to promote real choice while protecting people with Medicare from discrimination.

A plan is required to give a 60-day notice to affected enrollees if it removes a Medicare-covered prescription drug from its formulary or makes changes to its tiered cost-sharing structure during a plan year. If the notice requirement is not met, a plan must provide affected enrollees with a 60-day supply of the medication in dispute and a notice of the change when the enrollee requests a refill. Plans can set their own drug classifications. However, they are required to have more than one drug in their classifications.

Tiered Formularies

Some Medicare prescription drug plans may structure their plan with a preferred drug level also known as a tiered formulary. This is a formulary that has different cost-sharing amounts depending upon the drug that is being purchased. The lowest cost-sharing tier is tier 1 and subsequent tiers have higher cost sharing in ascending order. CMS will review drug categories to ensure there is no discrimination by drug plans discouraging enrollment of certain people with Medicare by placing drugs in a non-preferred tier. Plans must have exceptions procedures for formularies and tiered cost-sharing structures.

Exceptions Process

The exceptions process is different from an appeal or grievance. This is a process by which enrollees may have access to medically necessary Medicare-covered prescription drugs. There are two types of exceptions: tiering exceptions and formulary exceptions. An enrollee may request a tiering exception to obtain a Medicare covered prescription drug at a more favorable cost-sharing level, or a formulary exception to obtain a Medicare-covered prescription drug that is not on a plan's formulary. An enrollee's appointed representative may request a coverage determination (including an exceptions) or any appeal on behalf of the enrollee. A physician may request a standard or expedited coverage determination and an expedited redetermination on the enrollee's behalf without being the enrollee's authorized representative.

An enrollee may request an exception under the following circumstances:

- The enrollee is using a Medicare covered prescription drug on a plan's formulary that has been removed during the plan year for reasons other than safety
- The enrollee's physician prescribed a non-formulary Medicare-covered prescription drug for the enrollee that the physician believes is medically necessary because the formulary drug is medically inappropriate
- The enrollee is using a Medicare-covered prescription drug that has been moved during the plan year from the preferred to the non-preferred cost-sharing tier
- The enrollee's physician prescribed a Medicare-covered prescription drug for the enrollee that is included in a plan's more expensive cost-sharing tier because the prescribing physician believes the Medicare-covered prescription drug included in the less expensive cost-sharing tier is medically inappropriate for the enrollee. The enrollee can request an exception to obtain a non-preferred Medicare-covered prescription drug at the cost-sharing terms that apply at the preferred (but not generic) level.

The plan must notify the enrollee and the prescribing physician involved, as appropriate, of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours for expedited requests, or 72 hours for standard requests, after receipt of the request

for a coverage determination or receipt of the physician's oral supporting statement for exceptions requests.

A plan must provide an expedited coverage determination if it determines, or the enrollee's prescribing physician indicates, that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. If a plan does not make its determination within the appropriate timeframe, it must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe. Once a plan sponsor approves an exception request, it cannot require the enrollees to file additional exception requests for refills for the remainder of the plan year so long as the physician continues to prescribe the drug and it continues to be safe for treating the enrollee's condition. Plan sponsors are prohibited from assigning drugs approved under the exceptions process to a special formulary tier, co-payment, or other cost-sharing requirement.

5-Level Appeals Process

Level 1: Redetermination

Enrollee can request when the plan's initial coverage determination is unfavorable; plan has 7 days; can request expedited appeal, up to 72 hours

Level 2: Reconsideration

Enrollee can request when plan's redetermination is unfavorable; IRE has 7 days to make its decision; can request expedited appeal, up to 72 hours. The IRE must solicit the views of the prescribing physician whenever it processes either a standard or expedited reconsideration.

Level 3: Administrative Law Judge (ALJ)

Enrollee can request when IRE's determination is unfavorable; must meet amount in controversy requirement

Level 4: Medicare Appeals Council (MAC)

Enrollee can request when ALJ is unfavorable; MAC is entity within Department of Health and Human Services that reviews ALJ decisions

Level 5: Federal District Court

Enrollee may request when MAC is unfavorable; must meet amount in controversy

Coordination with Other Insurers

There will be a system of data sharing between Medicare, PDPs, SPAPS, GHPs, insurers, and other third-party arrangements. CMS is developing and implementing a coordination of benefits system including the facilitation of tracking out-of-pocket threshold costs that will enable pharmacies to obtain information about secondary insurers as well as the correct billing order.

Medigap

All issuers of Medigap prescription drug policies (whether standardized H, I, or J or pre-standardized or alternative standardized policies in the three waiver states, Minnesota, Massachusetts, and Wisconsin) must send a disclosure letter to all their policyholders with

prescription drug coverage telling them whether the coverage they currently have is creditable or not and what their options are based on this fact.

Because some pre-standardized policies contain drug coverage that is richer than the coverage provided by plans H, I, or J, these policies may meet or exceed the actuarial equivalence test for creditable coverage. The coverage provided by some of the drug coverage options available in the three waiver states similarly may be at least as rich as standard Medicare prescription drug coverage. Issuers of these policies, too, will have to send the “Yes, this is a creditable coverage” disclosure letter.

State Pharmacy Assistance Programs (SPAP) can provide wrap-around coverage to help people with Medicare enrolled in an SPAP with their prescription drug cost sharing. Therefore, SPAPs will be able to provide the same or better coverage for their enrollees at a lower cost per enrollee to the state. These savings can then be used to help reduce state budget costs or to expand the population served by their program. The law intends that all Medicare prescription drug plans in a state be given comparable opportunities to provide benefits in a particular state. Therefore, if an SPAP auto-enrolls its enrollees into a Medicare prescription drug plan, the costs incurred by the SPAP are not counted toward the out-of-pocket threshold. However, if the SPAP does not auto-enroll its participants in a Medicare prescription drug plan, any cost sharing provided by the SPAP can be applied toward the out-of-pocket threshold.

PACE, or Program of All-inclusive Care for the Elderly, combines medical, social, and long-term care services for frail people. The requirements for Medicare prescription drug coverage applies to PACE programs. Many of the Medicare prescription drug coverage requirements closely parallel those already in place under the PACE program. PACE organizations will be treated similarly to the MA-PD plans, and many of the administrative provisions will be waived for the PACE organizations. Although MMA requires cost-sharing responsibilities for people with Medicare, the PACE program exempts participants from paying deductibles, co-payments, coinsurance, or any other cost sharing.

Retirement Plans

People with Medicare who have retirement plans with prescription drug coverage may be concerned about losing those benefits with the implementation of Medicare prescription drug plans. A provision in MMA helps to address this issue. This is referred to as employment-related coverage options. Many times employment-related coverage is very generous. Medicare is working with employers to help people with Medicare keep their coverage through a current or former employer or union. The law provides incentives for employers and unions to continue offering coverage. Medicare is committed to facilitating effective coordination of Medicare and employment-based drug coverage to minimize administrative burdens and minimize costs to the taxpayers.

Customer Service

MMA incorporates substantial protections for people with Medicare from traditional Medicare and from the Medicare Advantage program. Some of them include:

Customer Service: Plans must provide a toll-free telephone number and place information on the internet; notify enrollees of how much prescription drug spending they had for the year and how close they are to reaching the catastrophic coverage limit

Pharmacy Access: Plans must provide convenient access no matter where enrollees live
 Medication Therapy Management: plans must have medication therapy management programs to help those who have multiple, chronic conditions, use multiple drugs and expect to have high drug costs make sure they are taking safe combinations of drugs

Generic Drug Information: Plans and pharmacists are required to inform enrollees if you they save money by using a generic drug

Privacy: Plans must maintain privacy and confidentiality of patient records

Uniform Benefits and Premiums: Plans must provide all enrollees in the plan with the same benefits and charge a community-rated premium

Formulary Protections: Formularies, or list of drugs the plan covers, must include two drugs from every therapeutic category and class with only a few exceptions

Plans are required to disseminate information on their drug coverage to their enrollees and prospective enrollees about their service areas, the benefits offered under the plan, the cost-sharing amounts, their formularies, pharmacy access, and other aspects of coverage available through the plan.

This information must be provided in writing, as well as on the Plan website and upon request through a toll-free call center.

There are a number of sources where you can get more information, including:

- Medicare's website for people with Medicare, www.medicare.gov
- Medicare's website for partners, www.cms.hhs.gov
- Order publications such as the Medicare & You handbook or Facts About Medicare Prescriptions Drug Plans. They can be ordered from the website or by calling 1-800-MEDICARE
- The toll-free number for Medicare, 1-800-MEDICARE (1-800-633-4227) and 1-877-486-2048 for TTY users